IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION - COLUMBUS

UNITED STATES OF AMERICA Plaintiff vs. THOMAS ROMANO, Defendant	Case No. 2:19-cr-202 Judge Michael H. Watson

UNITED STATES' MOTION FOR *DAUBERT* HEARING AND TO EXCLUDE TESTIMONY FROM DR. JAMES MURPHY

The United States of America, by and through counsel Christopher Jason and Andrew Barras, Trial Attorneys, United States Department of Justice, hereby seeks leave to file the following Motion for *Daubert* Hearing and to Exclude Testimony from Dr. James Murphy.

BACKGROUND[1]

On September 12, 2019, a federal grand jury returned a 20-count Indictment charging the defendant, Thomas Romano ("Romano"), with unlawfully dispensing and distributing controlled substances, in violation of 21 U.S.C. §§ 841(a)(1), (b)(1)(C). Each of these counts stem from prescriptions the defendant, a medical doctor, issued to seven individuals who were purported patients of a pain management clinic Romano operated under his name. On June 18, 2020, a federal grand jury returned a 34-count Superseding Indictment charging the defendant with unlawfully dispensing and distributing controlled substances to a total of 13 individuals through his purported medical clinic. Trial in this matter is scheduled for February 28, 2022.

[1] The government hereby incorporates by reference all of the factual allegations contained in the Indictment (R. 4) and the Superseding Indictment (R. 30) against the defendant.

On or around November 20, 2019, the government notified the defendant that it intended to call Dr. Timothy Munzing, M.D. ("Dr. Munzing") as an opinion witness in the fields of medical practice and the prescribing of controlled substances. On or around March 4, 2020, the government formally disclosed a copy of a 95-page initial report from Dr. Munzing, through which Dr. Munzing outlined his findings that the defendant has prescribed controlled substances outside the usual course of professional practice and without a legitimate medical purpose to the seven patients in the initial Indictment. The government subsequently provided the defendant with two additional reports in which Dr. Munzing outlined his findings that the defendant had prescribed controlled substances outside the usual course of professional practice and without a legitimate medical purpose to the additional six patients outlined in the Superseding Indictment. The government also provided an updated version of the first report that reflected that Dr. Munzing reviewed additional documents pertaining to the initial seven patients.[2] The defendant formally received all these materials on or before September 1, 2020, as well as all materials Dr. Munzing reviewed to reach his conclusions.

On June 18, 2021, defense counsel notified the government of the defendant's intent to call James Murphy, M.D. ("Dr. Murphy") as a defense expert at trial. The defendant provided a copy of Dr. Murphy's curriculum vitae at that time and indicated that a defense expert disclosure would be forthcoming upon completion of Dr. Murphy's review. On the afternoon of February 4, 2022, defense counsel produced a seven-page document entitled "Disclosure of Dr. James Patrick Murphy as Expert Witness." A copy of this disclosure is attached as Exhibit 1. This document outlines that Dr. Murphy reviewed medical file information for the seven patients whose

[2] This additional material is comprised of patient file information seized during the search warrant that was executed on the defendant's purported medical clinic, as well as produced by the defendant pursuant to a grand jury subpoena that was served concurrently with the execution of the search of the defendant's purported medical practice.

prescriptions formed the basis of the 20 counts in the initial Indictment, as well as "[f]ourteen additional patient records, provide (sic) to me by counsel." (Exh. 1, p. 2-3). The document also outlines that Dr. Murphy reviewed "Expert Review by Dr. Timothy Munzing, 8/13/2019." (Exh. 1, p. 3). The purported notice does not, however, outline that Dr. Murphy reviewed any of the patient information for the six additional patients whose prescriptions form the basis for the additional 14 counts in the Superseding Indictment. Moreover, the purported notice does not address whether Dr. Murphy reviewed Dr. Munzing's findings in his Updated First Report, his Second Report, or his Third Report in reaching his conclusions.

For the reasons outlined below, the government respectfully requests that the Court exclude the opinion testimony of Dr. Murphy or hold a *Daubert* hearing to determine whether Dr. Murphy's proffered testimony can satisfy the requirements of Federal Rule of Evidence 702.[3]

LEGAL STANDARD

Federal Rule of Evidence 702 states: "A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) The expert's scientific, technical, or specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) The testimony is based on sufficient facts or data;

(c) The testimony is the product of reliable principles and methods; and

(d) The expert has reliably applied the principles and methods to the facts of the case.

[3] The government recognizes that the Court's Standing Order requires that any *Daubert* motions be filed at least 45 days prior to the final pretrial conference. However, the delay in filing is due to the defendant's failure to provide any form of expert disclosure until 24 days prior to the final pretrial conference and was filed as soon as practical thereafter, and ahead of the February 16, 2022 motions deadline outlined in the final pretrial scheduling order.

Fed. R. Evid. 702. In *Daubert v. Merrell Dow Pharm. Inc.*, the United States Supreme Court held that Federal Rule of Evidence 702 imposes a "gatekeeping" obligation on the trial judge. 509 U.S. 579, 589 (1993). "Under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *United States v. Jones*, 107 F.3d 1147, 1156 (6th Cir. 1997), citing *Daubert*, 509 U.S. at 589; *see also Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 260 (6th Cir. 2001). In *Daubert*, the Supreme Court set out a non-exhaustive list of factors for determining the reliability of expert testimony:

1. Whether the expert's technique or theory can be or has been tested;
2. Whether the technique or theory has been subject to peer review and publication;
3. The known or potential rate of error of the technique or theory when applied;
4. The existence and maintenance of standards and controls; and
5. Whether the technique or theory has been generally accepted in the scientific community.

Daubert, 509 U.S. at 592-94. The proponent of the opinion testimony bears the burden of establishing that the evidence is admissible under Rule 702. *Bourjaily v. United States*, 483 U.S. 171 (1987); *see also Thomas v. Novartis Pharms. Corp.*, 443 Fed. Appx. 58, 61 (6th Cir. 2011).

As in *Daubert*, The Sixth Circuit Court of Appeals requires the district court to "determine whether the evidence 'both rests on a reliable foundation and is relevant to the task at hand.'" *Conwood Co., L.P. v. U.S. Tobacco Co.*, 290 F.3d 768, 792 (6th Cir. 2002), citing *Hardyman*, 243 F.3d at 260. Further, the Sixth Circuit has explained that this analysis "…involves a preliminary inquiry as to whether the reasoning or methodology underlying the testimony is scientifically valid and whether that reasoning or methodology properly can be applied to the facts in issue."

Conwood, 290 F.3d at 792, citing *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000); *see also In re: Scrap Metal Antitrust Litigation*, 527 F.3d 517, 529-30 (6th Cir. 2008).

To this same end, an opinion witness cannot offer purely vague and conclusory statements, without providing factual justification or methodological basis for the conclusions. "The task for the district court in deciding whether an expert's opinion is reliable is not to determine whether it is correct, but rather to determine whether it rests upon a reliable foundation, as opposed to, say, unsupported speculation." *In re: Scrap Metal Antitrust Litigation*, 527 F.3d at 529-30. The Advisory Committee's Notes to Federal Rule of Evidence 702 confirm that a "subjective, conclusory approach that cannot reasonably be assessed for reliability" that cannot be "challenged in some objective sense" is the type of testimony that bears scrutiny under the Supreme Court's first prong in *Daubert*. Fed. R. Evid. 702 Advisory Committee's Notes, 2000 Amendments. Courts have properly excluded opinion testimony on the basis that it is fundamentally conclusory and unsupported by scientific principles. In *Moore v. Ashland Chemical, Inc.*, the Fifth Circuit Court of Appeals upheld a trial court's exclusion of medical opinion testimony by a physician who sought to testify regarding the medical condition of the plaintiff. *Moore v. Ashland Chemical Inc.*, 151 F.3d 269, 278 (5th Cir. 1998). In so finding, the Fifth Circuit excluded this medical testimony because the opinion witness provided "no scientific support for his general theory" and "made no attempt to explain his conclusion…" *Id.* at 278-79. Further, the opinion witness's theory or methodology had not been tested or subject to peer review or publication, nor had it been shown to be generally accepted in the medical community. *Id*. at 279.

Finally, Federal Rule of Evidence 702(b) requires that expert testimony be "based on sufficient facts or data." This provision means that the expert must consider enough information to make the proffered opinion reliable and must base the opinion on at least the amount of data

that a reliable methodology demands. 29 Fed. Prac. & Proc. Evid. § 6268 Subdivision (b) (2nd ed.). The expert must also consider all the relevant data, and failure to consider all relevant data may render the expert's opinion unreliable. *Id*. "Included in the analysis under Rule 702(b) should be whether the expert ignored a significant portion of seemingly important data." *Id.*

ARGUMENT

A. Dr. Murphy's Opinions are Not Based on Sufficient Facts or Data to be Admissible

As a threshold and dispositive first issue, Dr. Murphy's proffered opinion testimony is inadmissible because Dr. Murphy has failed to review sufficient facts or data to credibly assist the triers of fact in making factual determinations in this case. Specifically, the defendant has failed to meet his burden of establishing the admissibility of Dr. Murphy's testimony because Dr. Murphy has not reviewed the medical file information for the six individuals[4] whose prescriptions are the subject of the Superseding Indictment, or Dr. Munzing's findings thereupon. Those prescriptions, as outlined below, comprise Counts 21 through 34 of the Superseding Indictment. The jury will also be asked to determine whether the defendant issued these prescriptions outside of the usual course of professional practice and without a legitimate medical purpose in violation of 21 U.S.C. § 841(a)(1) and (b)(1)(C). If permitted to testify, Dr. Murphy's failure to address these individuals' prescriptions will leave the jury with an incomplete and fundamentally skewed understanding of which prescriptions the defendant allegedly issued within the usual course of professional practice, and lead to undue confusion and/or speculation because Dr. Murphy failed to consider relevant evidence in rendering his medical opinion. The medical files for nearly half of the individuals to whom the defendant is alleged to have unlawfully prescribed controlled

[4] These individuals are identified by the following initials in the Superseding Indictment: K.C., M.R., E.W., B.W., J.P., and A.B.

substances is among the most important evidence in the case. Dr. Murphy's testimony therefore fails to meet the requirements of Federal Rule of Evidence 702(b) and should be excluded based on his failure to review significant portions of relevant evidence, or in the alternative a hearing should be held to determine whether Dr. Murphy has in fact reviewed sufficient facts and data to render a reliable opinion in this matter.

B. Dr. Murphy's Opinions are Not a Product of Reliable Principles and Methods

In addition to Dr. Murphy's conspicuous failure to review all the material relevant to the Superseding Indictment, Dr. Murphy has failed to provide sufficient explanation of his principles and methods to support admission of his testimony. In his expert disclosure, Dr. Murphy fails to cite any specific regulations, codes, or medical standards in support of any of his opinions. Rather, he cites his experience as a medical practitioner as the primary basis of his opinions in the case. Dr. Murphy states: "My opinions are based on my knowledge of this case, my experience as an anesthesiologist, addiction medicine specialist, and pain management specialist." (Exh. 1, p. 2). The only accredited medical institution[5] Dr. Murphy cites is the American Medical Association's ("AMA") Code of Medical Ethics, but in doing so, he inaccurately and misleadingly conflates the definition of a patient-physician relationship with the definition of "legitimate medical purpose" as it is applied in the Code of Federal Regulations, Section 1306.04(a). (Exh. 1, p. 3-4). Dr. Murphy further cites generally "the teachings of venerable physicians throughout the ages, foundational medical ethics, and respected bodies such as the American Medical Association, the World Health Organization, and the American Academy of Pain Medicine" in reaching his self-defined explanation of the "usual course of professional practice for a physician." (Exh. 1, p. 5). Dr. Murphy does not cite any specific findings, definitions, or even sources from which he reaches

[5] The government notes that even when citing the undisputedly credible American Medical Association, Dr. Murphy fails to cite a single specific source, but rather only vaguely cites the association generally.

this conclusion, let alone a reliable and peer-reviewed methodology.

Dr. Murphy's failures to provide any specific citations stand in stark contrast to Dr. Munzing's clear and thorough explanation of the medical references upon which he relies in forming his opinions in the case. In support of his methodology, Dr. Munzing cites foundational and generally-accepted published guidelines from the United States Centers for Disease Control and Prevention ("CDC") and the United States Food and Drug Administration ("FDA"), as well as persuasive guidelines and standards published by the American Society of Interventional Pain Physicians, the Medical Board of California Guidelines for Prescribing Controlled Substances for Pain, the Washington State Agency Medical Directors' Group, and the American Academy of Pain Medicine. Dr. Munzing also verifies his methodology by citing to his own peer-reviewed publication entitled the "Physician Guide to Appropriate Opioid Prescribing for Noncancer Pain."[6]

The closest Dr. Murphy comes to citing any sources (generally accepted, peer-reviewed, or otherwise) is when he notes that the CDC referred to its seminal 2016 guidance about appropriate opioid prescribing as "recommendations"[7] which are "voluntary, rather than prescriptive standards." (Exh. 1, p. 5). However, Dr. Murphy fails to note that in the same paragraph, the CDC explained that the 52-page guideline was published with the intent "to ensure that clinicians and patients consider safer and more effective treatment, improve patient outcomes such as reduced pain and improved function, and reduce the number of persons who develop opioid use disorder, overdose, or experience other adverse events related to these drugs." [citation to CDC guideline].

Significantly, Dr. Murphy fails to discuss any provisions of the CDC guidance or any other medical journal, regulation, guideline, or treatise of any type to support his vague and conclusory

[6] Perm J 2017;21:16-169. DOI: https://doi.org/10.7812/TPP/16-169.
[7] Dr. Murphy again failed appropriately cite this sentence, although it is found at page 4 of the cited guideline.

opinions. In lieu of a distinct and defined methodology, Dr. Murphy opines that medicine is essentially subjective: "Medicine is a science of uncertainty and an art of probability…Uncertainty in medicine is universal and judgment is often difficult. This has been known since the age of Hippocrates…" (Exh. 1, p. 4-5). Indeed, Dr. Murphy eschews any "published guideline" in forming his opinions in this case. (*See* Exh. 1, p. 5).[8]

The Advisory Committee's Notes to Federal Rule of Evidence 702 confirm that subjective opinion testimony of this sort should face heavy scrutiny: "If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" Fed. R. Evid. 702 Advisory Committee's Notes, 2000 Amendments, citing *Daubert v. Merrell Dow Pharmaceuticals*, 43 F.3d 1311, 1319 (9th Cir. 1995). Further, "the more subjective and controversial the expert's inquiry, the more likely the testimony should be excluded as unreliable." Fed. R. Evid. 702 Advisory Committee's Notes, 2000 Amendments, citing *O'Conner v. Commonwealth Edison Co.*, 13 F.3d 1090 (7th Cir. 1994) (expert testimony based on a completely subjective methodology held properly excluded).

Dr. Murphy's opinion evidence, as set forth in the expert disclosure, is inadmissible for all the grounds outlined above. Dr. Murphy fails to provide any methodological foundation for his findings beyond his subjective experience, and he fails to support his claims with any generally accepted or peer-reviewed medical criteria. In fact, the opinions in Dr. Murphy's expert disclosure

[8] Dr. Murphy's vague and conclusory expert disclosure has been the subject of litigation in at least one other jurisdiction. In *United States v. Zielke*, 2:17-cr-295-NBF (W.D.Pa. 2017), the government sought the exclusion of Dr. Murphy's opinion testimony based on similarly insufficient methodology and factual findings. *See* R. 129, "Motion for Daubert Hearing and to Exclude Testimony from Dr. James Murphy." However, the defendant in that matter entered a change of plea before the motion could be litigated. The government raises the issue to note the concerning apparent pattern of conduct in Dr. Murphy's expert disclosures.

are directly contradictory to many of the foundational principles from the CDC, FDA, and other medical guidelines outlined above. The Sixth Circuit has specifically noted that general acceptance of an opinion witness's methodology is relevant to determining the admissibility of that evidence: "[W]idespread acceptance can be an important factor in ruling particular evidence admissible, and a known technique that has been able to attract only minimal support within the community may properly be viewed with skepticism." *United States v. Bonds*, 12 F.3d 540, 560 (6th Cir. 1993). Moreover, Dr. Murphy provides no citation to any peer-reviewed or generally accepted publications that have published his methodology (or lack thereof). The Sixth Circuit found this to be a relevant factor in considering the admissibility of opinion testimony: "[S]ubmission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer-reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised." *Id.* at 560. For those reasons, Dr. Murphy's opinion testimony must be excluded, or there must be a *Daubert* hearing in which Dr. Murphy more thoroughly outlines the methodological foundation for any opinion he may render in the case.

C. Dr. Murphy Has Not Reliably Applied the Principles and Methods to the Facts of the Case

Finally, Dr. Murphy has failed to reliably apply his subjective principles and methods to the facts of the case. First, Dr. Murphy has not considered all the facts of the instant case insofar as he has not reviewed any of the information relevant to the Superseding Indictment. Second, Dr. Murphy's "analysis" is as much an opinion on what he believes the legal standards for "legitimate medical purpose" and "usual course of professional practice" should be. After inaccurately conflating a definition of "legitimate medical purpose" with an AMA definition of a patient-

physician relationship, Dr. Murphy attempts to define the "usual course of professional practice." After elaborating on the terms "standard of care" and "usual course of professional practice," Dr. Murphy inaccurately states that a departure from the usual course of professional practice is not "necessarily a criminal act." (Exh. 1, p. 4).[9] This definition is not only an incorrect statement of the law based on precedent of the United States Supreme Court and the Sixth Circuit Court of Appeals, but also a legal opinion rather than a medical opinion.

Third and most importantly, nothing in Dr. Murphy's expert disclosure actually applies his medical opinions to any specific facts or evidence in the case. Dr. Murphy fails to cite even a single page of the medical files Dr. Murphy claims to have reviewed. Instead, Dr. Murphy makes blanket and vague findings, including finding that "…Dr. Romano's treatment of the patients named in the indictment was in every instance consistent with the usual course of professional practice" and opining that "[t]hroughout the patient files I reviewed, including the seven patients named in the indictment, there is adequate evidence to support the devised plan of care." (Exh. 1, p. 4, 6). For factual support, Dr. Murphy notes only that "…the requisite information to justify treatments was discernable to me from information found throughout the patient clinical notes and additional data documented throughout the entire of the patient records." (Exh. 1, p. 6). Dr. Murphy makes vague allusions to evaluations, diagnoses, laboratory studies, treatments, and

[9] The United States Supreme Court has outlined that this kind of unlawful prescribing is exactly that which is contemplated under 21 U.S.C. § 841(a)(1). In the seminal case *United States v. Moore*, the Supreme Court found that medical practitioners can be held criminally liable under 21 U.S.C. § 841(a)(1) for unlawfully prescribing controlled substances. *United States v. Moore*, 432 U.S. 122 (1975). In so finding, the Supreme Court found that medical professionals are only authorized to prescribe controlled substances when they are registered with the DEA to do so, and that "[i]mplicit in the registration of a physician is the understanding that he is authorized only to act 'as a physician.'" *Moore*, 432 U.S. at 141. The Supreme Court ultimately held that "…the scheme of the statute, viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his 'professional practice.'" *Id.* at 140. The Sixth Circuit has repeatedly reaffirmed this finding. *See United States v. Volkman*, 797 F.3d 377, 386 (6th Cir. 2015) ("…knowingly distributing prescriptions outside the course of professional practice is a sufficient condition to convict a defendant under the criminal statutes relating to controlled substances.") (citing *United States v. Kanner*, 603 F3d. 530, 535 (8th Cir. 2010); *see also United States v. Godofsky*, 943 F.3d 1011 (6th Cir. 2019).

consultations in support of the defendant's conduct, but fails to identify any individuals for whom the defendant performed those services or the circumstances surrounding the circumstances in which those individuals did (or did not) appropriately receive those services. Because Dr. Murphy has failed to appropriately apply even his subjective methodology to adequate facts and evidence to support his opinion (as well as reviewing an inadequate set of facts and evidence), Dr. Murphy's opinion testimony must be excluded, or must be subject to a *Daubert* hearing whereby he can explain in sufficient detail the facts and evidence upon which he applied his so-called methodology in forming his opinions.

CONCLUSION

Because the defendant has failed to show that its proffered opinion witness, Dr. Murphy, meets the qualifications of Federal Rule of Evidence 702 for the reasons outlined above, the Court should exclude Dr. Murphy's testimony from this trial. In the alternative, the government respectfully requests a *Daubert* hearing to determine whether the defendant can meet its burden in establishing that Dr. Murphy's opinion testimony meets the standards outlined in Federal Rule of Evidence 702 for admission in the instant case.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 14th day of February, 2022, I filed the foregoing United States' Motion for Daubert Hearing and to Exclude Testimony of Dr. James Murphy with the Clerk of Court, and provided an electronic copy to the defendant's counsel of record.

By: *s/Christopher Jason*

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